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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,462	02/27/2002	Vincent Fischetti		5777

7590 06/18/2002  
Jonathan E. Grant  
Suite 210  
2120 L Street, N.W.  
Washington, DC 20037

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/083,462

Applicant(s)

FISCHETTI ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Preliminary Amendment A filed on February 27, 2002 is acknowledged.

Claims 15-26 are included in the prosecution of this application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 15 recites "A suppository enema for treating bacterial infections of the digestive tract, wherein said suppository enema is produced by the method of". The dependent claims recite composition claims. The examiner is unclear whether the claims are method claims or composition claims. The examiner suggests changing the claims to clarify whether the invention is a suppository or method of making claims.

Claim 26 depends on claim 27, which is a non-existent claim. The examiner is unclear what is being claimed.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 15-18 and 20-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Miyauchi (4900730) in combination with Monticello (5458876).**

Miyauchi teaches a rectal suppository containing lysozyme chloride for the gastrointestinal tract (Note abstract and example 37). The reference teaches the use of EDTA for increasing the absorption of the medicine (col. 5, lines 4-7). The reference teaches the pH range for the composition (note examples).

Miyauchi does not disclose the use of the lysozyme for the instant bacteria.

Monticello teaches a synergistic combination of a lantibiotic and lysozyme against microbial growth (*Listeria*) (Note abstract and example 1). The reference teaches lysozymes are cell wall degrading enzymes (col. 2, lines 28-33). Further, non-enzymatic preservatives such as EDTA are taught (col.2, lines 42-53). Monticello teaches the instant pH and teaches the combination of lysozyme and nysin (additional bactericidal agent as a function of pH and phosphate buffer is taught (Note fig. 1 and example II).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Miyauchi's lysozyme to digest the wall s of the instant

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bacteria since Monticello teaches the use of lysozymes to inhibit microbial growth such as Listeria by digesting the cell walls.

In the absence of showing the criticality of using citrate-phosphate buffer versus phosphate buffer, it is deemed obvious to one of ordinary skill in the art to use either since the prior art teaches the instant pH using a phosphate buffer.

**Claims 19 and rejected under 35 U.S.C. 103(a) as being unpatentable over Miyauchi (4900730) in combination with Monticello (5458876) in view of Goldstein et al (5861295).**

As set forth above, the references teach compositions containing lysozymes.

The references do not teach the use of instant reducing reagent.

Goldstein et al teach the method of producing thermostable enzymes. The reference teaches a filtration buffer solution containing EDTA and the dithiothreitol. The reference discloses that it is known to one of ordinary skill in the art to substitute buffer solutions as long as they have the equivalent effect (col. 8, lines 35-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use dithiothreitol and EDTA since Goldstein et al teach buffer solutions such as this are known to one of ordinary skill in the art.

### **Conclusion**


Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

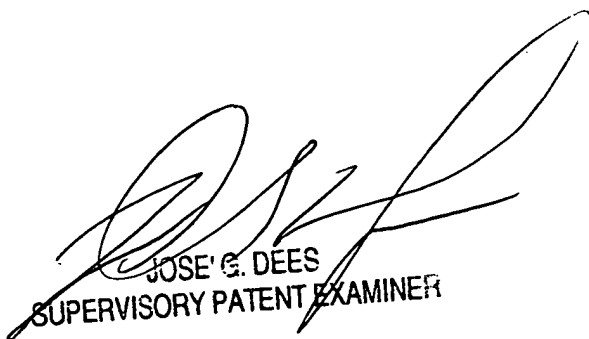
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If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG

  
June 13, 2002

  
JOSE C. DEES  
SUPERVISORY PATENT EXAMINER

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